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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,131

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Hassan Jomaa

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/676,131

Applicant(s)

JOMAA, HASSAN

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/673561
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12-31-03, 10-2-03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-11 are pending.

Claim Objections

Claim 11 is objected to because of the following informalities: Parenthetical expressions in claims line 1 and 26. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,680,308.

Although the conflicting claims are not identical, they are not patentably distinct from each other because '308 patent recite the very same compounds for the method of treating essentially the same infectious diseases. Possessing the teachings of '308,

one of ordinary skill in the art would have been motivated to employ the compounds of '308 in the method of treating herein claimed infectious diseases.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 provide for the use of organophosphoric compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

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protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 3 recites the broad recitation "alkanoyl radical", and the claim also recites "particularly preferably a formyl or acetyl radical" which is the narrower statement of the range/limitation.

Also claim 5 recites the broad recitation "atom A forms a chain of three carbon atoms", and the claim also recites "preferably a propylene, propenylene or hydroxypropylene" which is the narrower statement of the range/limitation.

Furthermore, claim 6 recites the broad recitation "metals of the first and second main group of the periodic system", and the claim also recites "preferably sodium, potassium, calcium or magnesium" which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "amino acids" (line 6), and the claim also recites "preferably ethanolamine" (line 6) which is the narrower statement of the range/limitation.

Also claim 7 recites the broad recitation "genus papovaviridae" (page3, line 3) and the claim also recites "in particularly preferably papova viruses, in particular papilloma viruses...miopapova viruses" (page3, line 3-6) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus herpesviridae" (page3, line 7), and the claim also recites "in particularly herpes simplex viruses... herpes virus 8" (page3, line 10) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus poxviridae" (page3, line 11), and the claim also recites "in particularly pox viruses" (page3, line 11) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "primary hepatotropic viruses" (page3, line 14), and the claim also recites "in particularly hepatitis viruses... hepatitis G viruses" (page3, line 17) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus picornaviridae" (page3, line 20), and the claim also recites "in particularly picorna viruses" (page3, line 21) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus calciviridae" (page3, line 24), and the claim also recites "in particularly hepatitis E viruses" (page3, line 24) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus reoviridae" (page3, line 25), and the claim also recites "in particularly reo viruses" (page3, line 26) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus togaviridae" (page3, line 27), and the claim also recites "in particularly toga viruses" (page3, line 27) which is the narrower statement of the range/limitation. Moreover, the claim recites the

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broad recitation "genus flaviviridae" (page3, line 29), and the claim also recites "in particularly flavi viruses" (page3, line 29) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus orthomyxoviridae" (page3, line 31), and the claim also recites "in particularly influenza viruses" (page3, line 31) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus paramyxoviridae" (page3, line 32), and the claim also recites "in particularly paramyxo viruses" (page3, line 32) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus rhabdoviridae" (page3, line 34), and the claim also recites "in particularly rhabdo viruses" (page3, line 35) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus coronaviridae" (page4, line 1), and the claim also recites "in particularly corona viruses" (page 4, line 1) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus bunyaviridae" (page 4, line 2), and the claim also recites "in particularly bunya viruses" (page 4, line 2) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus arenaviridae" (page4, line 4), and the claim also recites "in particularly arena viruses" (page 4, line 5) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus retroviridae" (page4, line 6), and the claim also recites "in particularly retro viruses" (page 4, line 6) which is the narrower statement of the range/limitation. Moreover, the claim recites the broad recitation "genus filoviridae"

(page 4, line 9), and the claim also recites "in particularly Marburg and Ebola viruses" (page 4, line 10) which is the narrower statement of the range/limitation.

Claim 8 recites the broad recitation "unicellular parasites" (line 2-3), and the claim also recites "namely pathogens of malaria... lambliosis" (line 3 to last line) which is the narrower statement of the range/limitation.

Claim 10 recites the broad recitation "active ingredient" (line 3), and the claim also recites "in particularly sulphonamide ... suramin" (last line) which is the narrower statement of the range/limitation.

Claim 11 recites the broad recitation "other cephalosporins" (line 8), and the claim also recites "cefsulodine... cefprozil" (line 9-10) which is the narrower statement of the range/limitation.

The term "so called wart viruses" in claim 7 renders the claim indefinite because it is unclear what viruses are encompassed by the claim.

The term "new oral cephalosporins with expanded spectrum" renders the claim indefinite because it is unclear what cephalosporin compounds encompassed by the claim.

Claim 11 is apparently in the form of Markush language. However, an "and" is apparently missing at the last line of the claim to indicate the relationship between group members (See MPEP 2173.05(h)).

Claim 11 contains the trademark/trade names Bay Y3118 and UK-109.496, and WR 238,605 (See page 41, line 28; page 42, line 5 and 15). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material

or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe several structurally different compounds and, accordingly, the identification/description is indefinite.

In order to expedite prosecution herein, claims 1-6, 9-11 drawn to the use of a organophosphorus compounds for the preparation of pharmaceutical composition will be treated on the merits herein, as method of preparation claims. In addition, claims 7-8, drawn to the use of a organophosphorus compounds for the treatment of infection will be treated on the merits herein, as method of treatment claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Imanaka et al. (US Patent 4,330,529, reference of record in the parent application) preparing the compositions containing organophosphoric compounds herein.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Camden (Camden (WO96/32115). See page 2, line 12-15, claim 6 for the method of treating HIV infection using the composition comprising the organophosphoric compounds herein)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kerst et al. (US Patent 3,887,353), reference of record in the parent application.

Kerst et al. teaches that diethyl beta-aminoethylphosphonate is a broad spectrum antimicrobial which can be used in a method to inhibit and/or prevent the growth of a variety of microorganisms (Abstract, line 1-3 and col. 1, under "Background of the Invention"). Kerst et al. suggest that the compound, diethyl betaaminoethylphosphonate, may have activity against other pathogens (See col.8, line 43-51).

Kerst et al. does not expressly teach the microorganism is a unicellular parasite.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to use diethyl betaaminoethylphosphonate in a method to treat unicellular parasitic infection.

One of ordinary skill in the art would have been motivated to use the compound of Kerst to treat parasitic infections herein because the compound is known to have antimicrobial activity against a wide variety of infecting microorganism including

parasites. Therapeutic activity against parasites herein would have been reasonably expected.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imanaka et al. (US Patent 4,330,529 from the Information Disclosure Statement received March 20, 2001) in view of Budavari (Merck Index 11th ed., monograph 3429).

Imanaka et al. teaches methods of preparing a composition containing 3-(N-formyl-N-hydroxyamino)propylphosphonic acid and a second antibiotic (See col. 13 and 14, examples 1-12).

Imanaka et al. does not expressly teach that the second antibiotic is doxycycline.

Budavari teaches that doxycycline is an antibiotic (See the Therap. Cat. section).

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate doxycycline into the method of Imanaka et al. to produce the composition herein.

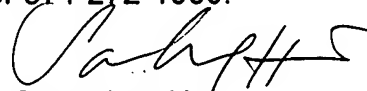
One of ordinary skill in the art would have been motivated to incorporate doxycycline into a method of preparing the instant composition because substituting the antibiotic, in the method of Imanaka et al., with any known antibiotics including doxycycline would be within the skill of artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


San-ming Hui
Primary Examiner
Art Unit 1617